



PATENT  
Attorney Docket: 056297-5012-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )  
 )  
 **Thomas GINGERAS et al.** )  
 )  
 Application No. **09/285,306** ) **Group Art Unit: 1637**  
 )  
 Filed: **April 2, 1999** ) **Examiner: C. Wilder**  
 )  
 For: **MYCOBACTERIAL RpoB SEQUENCES** )

Commissioner of Patents and Trademarks  
U.S. Patent and Trademark Office  
2011 South Clark Place  
Customer Window,  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, VA 22202

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(c)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed after the events recited in § 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final Office Action or a Notice of Allowance. The Commissioner is hereby authorized to charge **\$180.00** as specified by § 1.17(p) to Deposit Account No. 50-0310, for this Information Disclosure Statement under the provisions of 37 C.F.R. § 1.97(c).

Applicant respectfully requests that the Examiner initial and return the Form PTO-1449, indicating that the information has been considered and made of record herein.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute prior art. If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such document.

01/05/2005 AAD0F01 00000080 09285306  
01 FC:1806 180.00 DA

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.


If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 50-0310.

Dated: **January 4, 2005**

**Customer No. 000033522**  
1111 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004  
202-739-3000 (phone)  
202-739-3001 (fax)

Respectfully submitted,  
**MORGAN, LEWIS & BOCKIUS LLP**

By:

  
\_\_\_\_\_  
Bonnie Weiss McLeod  
Registration No. 43,255

<b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)  <b>PTO Form 1449</b>	Attorney Docket No. <b>056297-5012-01</b>	Application No.: <b>09/285,306</b>
	Applicant: <b>Thomas GINGERAS <i>et al.</i></b>	
	<b>PAGE 1 of 3</b>	
	Filing Date: <b>April 2, 1999</b>	Group Art Unit: <b>1637</b>

**U.S. PATENT DOCUMENTS**

Examiner Initial	1.	Document Number	Date	Name	Class	Sub Class	Filing Date
	1.	3,817,837	6/18/74	RUBENSTEIN <i>et al.</i>	195	103.5R	
	2.	3,850,752	11/26/74	SCHUURS <i>et al.</i>	95	103.5R	
	3.	3,939,350	2/17/76	KRONIC <i>et al.</i>	250	365	
	4.	3,996,345	12/7/76	ULLMAN <i>et al.</i>	424	12	
	5.	4,275,149	6/23/81	LITMAN <i>et al.</i>	435	7	
	6.	4,277,437	7/7/81	MAGGIO	422	61	
	7.	4,366,241	12/28/82	TOM <i>et al.</i>	435	7	
	8.	5,143,854	9/1/92	PIRRUNG <i>et al.</i>	436	518	
	9.	5,384,261	1/24/95	WINKLER <i>et al.</i>	436	518	
	10.	5,424,186	6/13/95	FODOR <i>et al.</i>	435	6	
	11.	5,445,934	8/29/95	FODOR <i>et al.</i>	435	6	
	12.	5,429,807	7/4/95	MATSON <i>et al.</i>	422	131	
	13.	5,436,327	7/25/95	SOUTHERN <i>et al.</i>	536	25.34	
	14.	5,545,531	8/13/96	RAVA <i>et al.</i>	435	6	
	15.	5,547,839	8/26/96	DOWER <i>et al.</i>			
	16.	5,700,637	12/23/97	SOUTH	435	6	
	17.	5,837,832	11/17/98	CHEE <i>et al.</i>	536	22.1	
	18.	5,795,716	8/18/98	CHEE <i>et al.</i>	435	6	
	19.	5,800,992	9/1/98	FODOR <i>et al.</i>	435	6	
	20.	5,861,242	1/19/99	CHEE <i>et al.</i>	435	5	

**FOREIGN PATENT DOCUMENTS**

	21.	Document Number	Date	Country	Class	Sub Class	<u>Translation</u> YES NO
	21.	89/10977	11/16/89	WO			
	22.	90/15070	12/13/90	WO			
	23.	92/10092	6/25/92	WO			
	24.	94/12305	6/9/94	WO			
	25.	94/10128	5/11/94	WO			

Examiner	Date Considered
----------	-----------------

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary) <b>PTO Form 1449</b>		Attorney Docket No. <b>056297-5012-01</b>	Application No.: <b>09/285,306</b>
Applicant: <b>Thomas GINGERAS et al.</b>		<b>PAGE 2 of 3</b>	
Filing Date: <b>April 2, 1999</b>		Group Art Unit: <b>1637</b>	

OFFICE  
 JAN 04 2005  
 PATENT & TRADEMARK OFFICE

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
27.	Barringer, <i>et al.</i> , "Blunt-end and single-strand ligations by <i>Escherichia coli</i> ligase: influence on an in vitro amplification scheme", <u>Gene</u> , Vol. 89 (1990), pp. 117-122.
28.	Beattie, <i>et al.</i> , "Genosensor Technology", <u>Clinical Chemistry</u> , Vol. 39, No. 4 (1993), pp. 719-722.
29.	Bloch, <i>et al.</i> , "Nationwide Survey of Drug-Resistant Tuberculosis in the United States", <u>JAMA</u> , Vol. 271, No. 9 (March 2, 1994), pp. 665-671.
30.	Chetverin, <i>et al.</i> , "Oligonucleotide Arrays: New Concepts and Possibilities", <u>Bio/Technology</u> , Vol. 12 (November 1994), pp. 1093-1099.
31.	Elder, "Analysis of DNA Oligonucleotide Hybridization Data by Maximum Entropy", Proceedings of the Twelfth International Workshop on Maximum Entropy and Bayesian Methods, Kluwer Academic Publishers, 1992.
32.	Fodor, <i>et al.</i> , "Light-Directed Spatially Addressable Parallel Chemical Synthesis", <u>Science</u> , Vol. 251 (1991), pp. 767-773.
33.	Fodor, <i>et al.</i> , "Multiplexed Biochemical Assays with Biological Chips", <u>Nature</u> , Vol. 364 (August 5, 1993), pp. 555-556.
34.	Felmlee, <i>et al.</i> , "Genotypic Detection of <i>Mycobacterium tuberculosis</i> Rifampin Resistance: Comparison of Single-Strand Conformation Polymorphism and Dideoxy Fingerprinting", <u>Jrnl. Clin. Microbiology</u> , Vol. 33, No. 6 (1995), pp. 1617-1623.
35.	Gingeras, <i>et al.</i> , "Simultaneous Genotyping and Species Identification Using Hybridization Pattern Recognition Analysis of Generic <i>Mycobacterium</i> DNA Arrays", <u>Genome Research</u> , Vol. 8 (1998), pp. 435-448.
36.	Guatelli, <i>et al.</i> , "Isothermal, <i>in vitro</i> amplification of nucleic acids by a multienzyme reaction modeled after retroviral replication", <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 87 (March 1990), pp. 1874-1878.
37.	Hughes, <i>et al.</i> , "Identification of Mycobacteria from Animals by Restriction Enzyme Analysis and Direct DNA Cycle Sequencing of Polymerase Chain Reaction-Amplified 16S rRNA Gene Sequences", <u>Jrnl. Clin. Microbiology</u> (December 1993), pp. 3216-3222.
38.	Hoffner, "Pulmonary Infections Caused by Less Frequently Encountered Slow-Growing Environmental Mycobacteria", <u>Euro. Jrnl. Clin. Microbiol. Infect. Dis.</u> , Vol. 13, No. 11 (November 1994), pp. 937-941.
39.	Hunt, <i>et al.</i> , "Detection of a Genetic Locus Encoding Resistance to Rifampin in Mycobacterial Cultures and in Clinical Specimens", <u>Diagn. Microbiol. Infect. Dis.</u> , Vol. 18 (1994), pp. 219-227.
40.	Jonas, <i>et al.</i> , "Detection and Identification of <i>Mycobacterium tuberculosis</i> Directly from Sputum Sediments by Amplification of rRNA", <u>Jrnl. Clin. Microbiology</u> (September 1993), pp. 2410-2416.
41.	Kanal, "Patterns in Pattern Recognition", <u>IEEE Trans. Info. Theory</u> (1974), pp. 697-722.
42.	Kapur, <i>et al.</i> , "Rapid <i>Mycobacterium</i> Species Assignment and Unambiguous Identification of Mutations Associated with Antimicrobial Resistance in <i>Mycobacterium tuberculosis</i> by Automated DNA Sequencing", <u>Arch. Pathol. Lab. Med.</u> (February 1995), Vol. 119, pp. 131-138.
43.	Kox, <i>et al.</i> , "PCR Assay Based on DNA Coding for 16S rRNA for Detection and Identification of Mycobacteria in Clinical Samples", <u>Jrnl. Clin. Microbiol.</u> (1995), pp. 3225-3233.
44.	Kwoh, <i>et al.</i> , "Transcription-based amplification system and detection of amplified human immunodeficiency virus type 1 with a bead-based sandwich hybridization format", <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 86 (February 1989), pp. 1173-1177.
45.	Landegren, <i>et al.</i> , "A Ligase-Mediated Gene Detection Technique", <u>Science</u> , Vol. 241 (August 26, 1988), pp. 1077-1080.

Examiner	Date Considered
Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

<b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)  PTO Form 1449		Attorney Docket No. <b>056297-5012-01</b>	Application No.: <b>09/285,306</b>
Applicant: <b>Thomas GINGERAS et al.</b>		<b>PAGE 3 of 3</b>	
Filing Date: <b>April 2, 1999</b>		Group Art Unit: <b>1637</b>	

OFFICE  
 JAN 04 2005  
 RECEIVED

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
46.	Lipshutz, <i>et al.</i> , "Using Oligonucleotide Probe Arrays to Access Genetic Diversity", <u>Biotechniques</u> , Vol. 19, No. 3 (1995), pp. 442-447.
47.	Lipshutz, <i>Clin. Chem.</i> , Vol. 40, No. 6 (1994 Abstract), p.1173.
48.	Musser, "Antimicrobial Agent Resistance in Mycobacteria: Molecular Genetic Insights", <u>Clinical Microbiology Reviews</u> (October 1995), pp. 496-514.
49.	Pease, <i>et al.</i> , "Light-Generated oligonucleotide arrays for rapid DNA sequence analysis", <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 91 (May 1994), pp. 5022-5026.
50.	Plikaytis, <i>et al.</i> , "Differentiation of Slowly Growing <i>Mycobacterium</i> Species, Including <i>Mycobacterium tuberculosis</i> by Gene Amplication and Restriction Fragment Length Polymorphism Analysis", <u>Jrnl. Clin. Microbiology</u> (July 1992), pp. 1815-1822.
51.	Salazar, <i>et al.</i> , "Nucleic acid scanning-by-hybridization of enterohemorrhagic <i>Escherichia coli</i> isolates using oligodeoxynucleotide arrays", <u>Nucleic Acids Res.</u> , Vol. 24, No. 24 (1996), pp. 5056-5057.
52.	Schirm, <i>et al.</i> , "Comparison of Amplicor, In-House PCR, and Conventional Culture for Detection of <i>Mycobacterium tuberculosis</i> in Clinical Samples", <u>Jrnl. Clin. Microbiology</u> (1995), pp. 3221-3224.
53.	Sewell, <i>et al.</i> , "Comparison of the Septi-Chek AFB and BACTEC Systems and Conventional Culture for Recovery of Mycobacteria", <u>Jrnl. Clin. Microbiology</u> (October 1993), pp. 2689-2691.
54.	Schafer, <i>et al.</i> , " <i>Mycobacterium xenopi</i> , <i>Mycobacterium fortuitum</i> , <i>Mycobacterium kansasii</i> , and Other Nontuberculous Mycobacteria in an Area of Endemicity fo AIDS", <u>Clin. Infect. Dis.</u> (1992), pp. 161-162.
55.	Southern, <i>et al.</i> , "Analyzing and Comparing Nucleic Acid Sequences by Hybridization to Arrays of Oligonucleotides: Evaluation Using Experimental Models", <u>Genomics</u> (1992), pp. 1008-1017.
56.	Small, <i>et al.</i> , "Molecular Epidemiology of Tuberculosis", <u>Tuberculosis: Pathogenesis, Protection and Control</u> (1994), pp. 569-582.
57.	Stager, <i>et al.</i> , "Role of Solid Media When Used in Conjunction with the BACTEC System for Mycobacterial Isolation and Identification", <u>Jrnl. Clin. Microbiol.</u> (January 1991), pp. 154-157.
58.	Telenti, <i>et al.</i> , "Detection of rifampicin-reistance mutations in <i>Mycobacterium tuberculosis</i> ", <u>The Lancet</u> , Vol. 341 (March 13, 1993), pp. 647-650.
59.	Van der Vliet, <i>et al.</i> , "Nucleic acid sequence-based amplification (NASBA) for the identification of mycobacteria", <u>Journal of General Microbiology</u> , Vol. 139 (1993), pp. 2423-2429.
60.	Wolinsky, "Mycobacterial Diseases Other Than Tuberculosis", <u>Clinical Infectious Diseases</u> , Vol. 15 (1992), pp. 1-12
61.	Wu, <i>et al.</i> , "The Litigation Amplification Reaction (LAR) – Amplification of Specific DNA Sequences Using Sequential Rounds of Template-Dependant Ligation", <u>Genomics</u> , Vol. 4 (1989), pp. 560-569.
62.	Whelen, <i>et al.</i> , "Direct Genotypic Detection of <i>Mycobacterium tuberculosis</i> Rifampin Resistance in Clinical Specimens by Using Single-tube Heminested PCR", <u>Jrnl. Clin. Microbiology</u> , Vol. 33, No. 3 (1995), pp. 556-561.

Examiner	Date Considered
----------	-----------------

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.